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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/006,796	12/04/2001	Eija Pirhonen	01942-00007	9843
22910 7590 04/17/2008 BANNER & WITCOFF, LTD. 28 STATE STREET 28th FLOOR BOSTON, MA 02109-9601				
EXAMINER				
YOUNG, MICAH PAUL				
ART UNIT		PAPER NUMBER		
1618				
MAIL DATE		DELIVERY MODE		
04/17/2008		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

**Application No.**

10/006,796

**Applicant(s)**

PIRHONEN ET AL.

**Examiner**

MICAH-PAUL YOUNG

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 16 January 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-13 and 15-17 is/are pending in the application.
- 4a) Of the above claim(s) 2 and 9 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 3-8, 10-13 and 15-17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SF/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

**Acknowledgment of Papers Received:** Amendment/Response dated 1/16/08.

#### ***Election/Restrictions***

Newly submitted claims 2 and 9 directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the claims recite a rigid polymer matrix with a porous surface and a non-porous core. The implant does not comprise a plasticizer. Claims 1, 3-8, 10-13 and 15-17 comprise a plasticizer compound included into the matrix and is essentially non-porous throughout the matrix. The plasticizer containing implant is softer and more malleable than the porous implant of claims 2 and 9.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 2 and 9 withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3-8, 10-13 and 15-17 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The newly amended claims now recite that the plasticizer is dispersed within the rigid matrix only at the surface of the implant. This is a contradictory statement. How can the

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plasticizer be dispersed within the matrix, implying a complete penetration and distribution of the plasticizer yet only be present on the surface of the implant? Clarification is required.

The terms "flexible and rigid" in claims 1, 2, 9 and 10 are relative terms which renders the claim indefinite. The terms "flexible and rigid" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. These terms are used to refer to the stiffness of the implant material however without a value for the elastic modulus, or bending resistance they are merely relative terms with no way of determining their significance. Gold is more rigid than a gel, yet less rigid than titanium. There is no clear distinction in the claims to determine how flexible and/or rigid an implant would need to be in order to meet the limitations of the claims. Correction is required.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the

reference is determined under 35 U.S.C. 102(c) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1, 3-8, 10-13, and 15-17 are rejected under 35 U.S.C. 102(e) as being anticipated by Niederauer et al (USPN 6,344,496 hereafter '496). The claims are drawn to an implant comprising a biodegradable polymer matrix, a drug and a plasticizer such as N-methyl-2-pyrrolidone. The claims are to a method of making the implant comprising forming a biodegradable implant and adding a plasticizer to the formed implant.

The '496 patent teaches a biodegradable implant material used for guiding tissue regeneration, comprising a biodegradable copolymer such as PLA/PGA and active agents such as growth factors enzymes and antibiotics (col. 8, lin. 23-48; examples). The implant is formed into films or strips that are cured and solidified. The films are next soaked in a plasticizer such as N-methyl-2-pyrrolidone (col. 9, lin. 45-50). The implants are soaked into the plasticizer long enough to allow them to be malleable enough to conform to any shape required. The implant stiffens once the plasticizer is removed by co-solvent, either from the body during implantation or beforehand (*Ibid*). Since the film is only soaked long enough to make it malleable, the plasticizer is not present throughout the matrix. Bioactive bioglass is added to the implant as an active agent and can be added before, during and after the solvent precipitation step (example 4). The solid rigid implant is used as cartilage replacements, tissue scaffolds or osteochondral implants (col. 6, lin. 48-59).

These disclosures render the claims anticipated.

***Response to Arguments***

Applicant's arguments filed 1/16/08 have been fully considered but they are not persuasive. Applicant argues that:

The '496 patent cannot inherently anticipate the instant claims since it has not been established that the nonporous core is necessarily present in the '496 patent.

Regarding the argument, as discussed above the '496 patent discloses an implant comprising a biodegradable polymer and a plasticizer soaked into the surface of the implant. Applicant argues that the implant material so of the '496 would not necessarily possess a porous surface and non-porous core, whoever these claims are drawn to a non-elected invention. As indicated in the previous Office action the claims were being interpreted as an implant comprising a plasticizer. The implant comprising the plasticizer is essentially non-porous since the plasticizer is still present and has not seeped out leaving behind pores. This implant is taught by the '496 patent. The '496 patent teaches an implant made with the same biodegradable polymers, soaked in the same plasticizer and incorporating the same active ingredients as the instant claims. Applicant argues that the implant is submerged in the plasticizer for a short period of time however this is not represented in the claims. The claims merely recite that the plasticizer is present in the implant. For these reasons the claims remain anticipated.

### *Conclusion*

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICAH-PAUL YOUNG whose telephone number is (571)272-0608. The examiner can normally be reached on Monday-Friday 7:00-4:30; every other Monday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/  
Supervisory Patent Examiner, Art Unit 1618  
/MICAH-PAUL YOUNG/  
Examiner, Art Unit 1618